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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/716,098	11/17/2003	Douglas John Meldrum Allen	62815-A-PCT-US/JPW/GJG/AC	4866

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EXAMINER	
TRUONG, TAMTHOM NGO	
ART UNIT	PAPER NUMBER
1624	

MAIL DATE	DELIVERY MODE
07/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/716,098	ALLEN ET AL.	
	Examiner	Art Unit	
	Tamthom N. Truong	1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *12,13 and 16-26* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *12,13,16 and 23-26* is/are rejected.

7)☒ Claim(s) *17-22* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment of 4-12-07 has been fully considered. The amended claim 25 has overcome the previous rejection of 112/2nd item (b). The terminal disclaimer has also overcome the previous rejection of Obviousness-type Double Patenting.

While the specification provides a definition for "hyperproliferative disorder", the unduly broad scope of such a category raises the issue of enablement. Claims 12 and 16 also have the same scope with claim 2 of US'721, thus, presents another new ground of rejection.

Claims 12, 13 and 16-26 are pending.

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 13 recites the limitation "hydrate form" of the salt in claim 12. There is insufficient antecedent basis for this limitation in the claim. Note, claim 12 does not recite such a form.

Claim Rejections - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly

connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. **Scope of Enablement:** Claims 23-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating certain cancers such as breast, ovarian, colorectal, prostate, and lung cancer, does not reasonably provide enablement for a method of treating all hyperproliferative disorders. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The following factors have been considered in the determination of an enabling disclosure:

(1) The breadth of the claims;

(2) The amount of direction or guidance presented;

(3) The state of the prior art;

(4) The relative skill of those in the art;

(5) The predictability or unpredictability of the art;

(6) The quantity of experimentation necessary;

[See ***Ex parte Forman***, 230 USPQ 546 (Bd. Pat. App. & Int., 1986); also ***In re Wands***, 858 F. 2d 731, 8 USPQ 2d 1400 (Fed. Cir. 1988)].

The breadth of the claims: Claim 23 recites a "method of treating a mammal suffering from a hyperproliferative disorder..." The term "hyperproliferative disorder" covers all types of tumors, cancers as well as other diseases. Examples of various tumors and cancers include

Lymphoblastic Leukemia, Myeloid Leukemia, Adrenocortical Carcinoma, Hepatocellular Cancer, Liver Cancer, Hodgkin's Disease, Hodgkin's Lymphoma, Non-Hodgkin's Lymphoma, Soft Tissue Sarcoma, AIDS-related Maglinancies, Anal Cancer, Astrocytoma, Bile Duct Cancer, Bladder Cancer, Bone Cancer, Brain Tumors, Breast Cancer, CNS Lymphoma, Cerebellar Astrocytoma, Cerebral Astrocytoma, Cervical Cancer, Medulloblastoma, Pancreatic Cancer, Endometrial Cancer, Ewing's Sarcoma, Gastric Cancer, Germ Cell Tumors, Gestational Trophoblastic Tumors, Hairy Cell Leukemia, Head and Neck Cancer, Intraocular Melonoma, Hypopharyngeal Cancer, Intestinal Cancer, Kaposi's Sarcoma, Kidney Cancer, Laryngeal Cancer, Lung Cancer, Osteosarcoma, Skin Cancer, Retinoblastoma, Rhabdomyosarcoma, Thyoma,... etc.

Thus, the scope of claims 23 and dependent claims thereon is unduly broad.

The amount of direction or guidance presented: The claimed compound inhibits epidermal growth factor receptor (EGFR), erbB2, HER3 or HER4. Said receptors are found in cancers such as: breast, ovarian, colorectal, prostate and lung cancer. The specification does not provide data or evidence on reduction of tumor size or cell growth for other cancers that are not related to the cited receptors.

The state of the prior art: The claimed compound is commercially known as Iressa or Gefitinib which, in a preclinical studies, is shown to treat cancers such as: prostate, ovarian, breast, colon, small-cell and non-small-cell lung, and ductal carcinoma. Even for the listed cancers, "only tumors in which inhibition of the receptor results in inhibition of down stream

signaling pathways are growth arrested." (see page 861 (right column), **Grünwald V. et. al.**, REVIEW, J. Nat. Can. Inst., Vol. 95, No. 12, 6/18/03). Thus, the state of the art does not correlate the inhibition of EGFR to all types of cancers as encompassed by the term "hyperproliferative disorder". Therefore, the state of the art does not support the scope of the claimed method.

The relative skill of those in the art: There has never been a compound capable of treating cancer generally, let alone treating all kinds of "hyperproliferative disorder". Different types of cancers affect different organs and have different modes of growth and harm to the body as well as different vulnerabilities. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Therefore, it is beyond the skill of oncologists today to get an agent to be effective against all cancers or all hyperproliferative disorders in general.

The predictability or unpredictability of the art & The quantity of experimentation necessary: The pharmaceutical art has been known for its unpredictability due to various conflicting path ways, or biological factors that are sometimes genetically unique to individuals. In the instant case, the showing of EGFR inhibition alone does not guarantee the compound's effectiveness in treating cancers that are not related to EGFR.

See ***Hoffman v. Klaus*** 9 USPQ 2d 1657, and ***Ex parte Powers*** 220 USPQ 925 regarding type of testing needed to support *in vivo* uses.

Thus, given the unpredictable nature of the art, and the preliminary research in the art, one skilled in the art will have to carry out undue experimentation to practice the method of treatment recited in claim 23. When the best efforts have failed to achieve a goal, it is reasonable

for the PTO to require evidence that such a goal has been accomplished, ***In re Ferens***, 163 USPQ 609. The failure of skilled scientists to achieve a goal is substantial evidence that achieving such a goal requires undue experimentation, ***Genetech vs. Novo Nordisk***, 42 USPQ 2nd 1001, 1006.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A **statutory type** (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 12 and 16 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 2 and 9 of prior U.S. Patent No. 6,706,721 B1. This is a double patenting rejection. Although the instant claim 12 does not recite the term "anhydrous form", such a form is the only form disclosed in the specification. The dosage range recited in the instant claim 16 is exactly disclosed in the specification of US'721 B1.

Claim Objections

3. Claims 17-22 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 571-272-0676. The examiner can normally be reached on M, T and Th (9:00-5:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Tamthom N. Truong
Examiner
Art Unit 1624

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7-6-07

EMILY BERNHARDT
PRIMARY EXAMINER
GROUP 1600